Proposal Number: IN/CBE/QUOTE/2016/40
Dated: 7th July '2016

To,
The Principal,
Government Madhav Science P.G. College,
Dewas Road, Ujjain,
Madhya Pradesh, India

Sub: Proposal for 'Awareness Training on WHO GMP guidelines for Pharmaceutical products'

Respected Sir,

Thank you so much for showing interest in our services. Based on our discussion with Dr. Arpan Bhardwaj, we are pleased to present as below the charges for WHO GMP training alongwith applicable terms & conditions.

TRAINING COURSE DETAILS:

- **Course Title**: WHO GMP Awareness Training Course
- **No. of participants:** 20 nos. (max)
- **Preferred Facilities for conducting the course:** Conference room / Auditorium, LCD Projector, White Board, White Board Markers, Pointer, Flip Charts.
- **Deliverables:** Participants shall be required to appear for examination at the end of training course. Certificates will be awarded to participants successfully clearing the examination.

Total Charges:

Sr. No.	Activity	Duration	Charges (INR)
1.	**Awareness Training on WHO GMP guidelines for Pharmaceutical products**	**2 man-days**	**45,000**
		Total Charges	**INR 45,000/-**

***Note:**

1. **Taxes** - Service Tax as applicable will be charged extra at actual as per government norms.
2. **Travel & Sojourn** – Travel & Sojourn Cost of Trainer will be charged extra at actual in addition to above charges. Accomodation & Local Conveyence for Trainer needs to be arranged by your company.
3. **Payment Terms** – 100 % of the total charges mentioned above are payable in advance. Balance payment towards Travel & Sojourn Cost, Service Tax to be paid within 15 days after receipt of invoice upon completion of training.
4. **Validity of Proposal -** 30 Days from the date of this offer

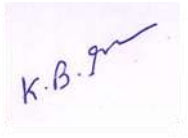
CLIENTELE:

SGS FEELS PROUD TO BE ASSOCIATED WITH RENOWNED COMPANIES LIKE CIPLA, PROCTER AND GAMBLE, USV PHARMA, GLAXO, IDEAL CURES, SHRIJI POLYMERS, NESTLE, UNILEVER, PEPSICO, VEDANTA, NPC, ALSTOM, PHILIPS, COCA-COLA, DHL, H&R JOHNSON, HLL LIFECARE, MONSANTO, VARDHMAN HEALTH SPECIALITIES, BRITISH BIOLOGICALS, NTPC, TRIVITRON HEALTHCARE, NOVARTIS, APTAR PHARMA, LOREAL, TTK, FIRMENICH, HINDUSTAN NATIONAL GLASS, AEGIS LOGISTICS, ICICI BANK, FAURECIA, HERTZ CHEMICALS, TERUMO PENPOL

Signature Not Verified
ARPAN BHARDWAJ
E=ARPANBHARDW
AJ11@GMAIL.COM,

Incase you require any further clarifications / additional information, please feel free to contact us.
Thanking you and assuring our best of services always,

Yours sincerely,
For SGS India Pvt Ltd



Kaival Shah
Assistant Manager - Sales
M: +91 8128694331
Email: kaival.shah@sgs.com

ACCEPTANCE:

On behalf of **M/s Government Madhav Science P.G. College, Ujjain**

We confirm hereby that the terms & conditions mentioned in the proposal is acceptable & agree to pay all costs as stated in this offer.

Name: **Position:**

Signature: **Date:**

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ARPAN BHARDWAJ
E=ARPANBHARDW
AJ11@GMAIL.COM,

No. _____ Date: _____

List of participants in two days training program on WHO- GMP participation

S. No.	STUDENT NAME LIST	Class
1.	Mr. Mahendra Singh Gehlot	M.Sc. I sem
2.	Mr. Rajesh Malviya	M.Sc. I sem
3.	Mr. Rakesh Anjana	M.Sc. I sem
4.	Miss Reshma Mansharamani	M.Sc. I sem
5.	Mr. Kamal Kamodia	M.Sc. I sem
6.	Miss Upama Tiwari	M.Sc. I sem
7.	Miss Priyanka Chouhan	M.Sc. I sem
8.	Miss Pooja Varnasiya	M.Sc. I sem
9.	Miss Varsha Choudhary	M.Sc. I sem
10.	Mr. Manohar Singh Anjana	M.Sc. I sem
11.	Miss Aayushi Patidar	M.Sc. I sem, GDC
12.	Miss Mayuri Soner	M.Sc. I sem, GDC
13.	Miss Neha Shrivastava	M.Sc. I sem, GDC
14.	Miss Anita Rajora	M.Sc. I sem, GDC
15.	Miss Divya Gurjar	M.Sc. III sem
16.	Mr. Rajesh Waghela	M.Sc. III sem
17.	Mr. Abhishek Choursiya	M.Sc. III sem
18.	Mr. Vasudev Soni	M.Sc. III sem
19.	Miss Neha Kashyap	M.Sc. III sem
20.	Mr. Satish patidar	M.Sc. III sem
21.	Miss Anjali Tiwari	M.Sc. III sem
22.	Miss Kajal Pandey	M.Sc. IV sem
23.	Miss Surbhi Shukla	M.Sc. IV sem
24.	Mr. Kishor Singh Hada	M.Sc. IV sem
25.	Mr. Yogesh Bairagi	B.Sc. III sem
26.	Mr. Sanjay Gyani	Alchemy chemicals, Ujjain
27.	Mr. Nipun Maheshwari	Osmed formulations
28.	Mr. Mitesh Ladha	Vintochem Pharma
29.	Mr. Meghant Jain	Super Pharma Products
30.	Mr. Ashok Jain	Zurich Health Care
31.	Dr. Piyush Tiwari	India Phosphate, Ujjain
32.	Mr. Sushil Rathor	Shriji Polimer, Ujjain
33.	Mr. Arvind Singh Sisodiya	Sun Pharma, Dewas
34.	Mrs. Komal Chelaramani	Faculty
35.	Miss Priyanka Khare	Faculty
36.	Miss Shruti Sharma	Faculty
37.	Miss Namrata Vyas	Faculty

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GMP

GOOD MANUFACTURING PRACTICES

A Quality system for assuring

A Quality Product

WHEN YOU NEED TO BE SURE SGS

SGS AGENDA

- What is cGMP?
- Various guidelines related to cGMP
- Self Inspection
- Conducting Internal Audits
- Approaches / style of current regulatory inspections
  - direct interaction of inspectors with the Doers at shop-floor.

IS YOUR MEDICINE SAFE ????

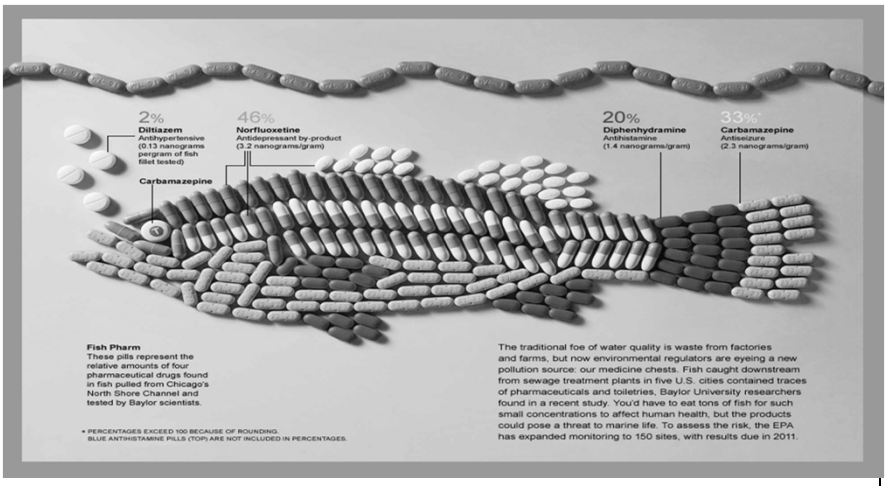

*Image from *National Geographic, April 2010*

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WHAT IS GMP?

- Good Manufacturing Practice is a set of regulations, codes, and guidelines for the manufacture of drug substances and drug products, medical devices, in vivo and in vitro diagnostic products, and foods.

Fig.4 GMP handbooks for every industry

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GOOD MANUFACTURING PRACTICES WORLDWIDE ENFORCEMENT

- Good Manufacturing Practices are enforced in the United States by the FDA
- In the United Kingdom by the Medicines and Healthcare Products Regulatory Agency
- GMPs are enforced in Australia by the Therapeutically Goods Administration
- In India by the Ministry of Health, multinational and/or foreign enterprises

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A TIME LINE OF GMP

- 1902 - Development of the Biologic Control Act
- 1906 - Development of the Pure Food and Drug Act
- 1938 - Federal Food, Drug and Cosmetic Act
- 1941 - Initiation of GMP
- 1944 - Development of Public Health Services Act
- 1962 - Kefauver-Harris Drug Amendments released
- 1963 - Establishment of GMPs for Drugs
- 1975 - CGMPs for Blood and Components Final Rule
- 1976 - Medical Device Amendments
- 1978 - CGMPs for Drugs and Devices
- 1979 - GLPs Final Rule
- 1980 - Infant Formula Act is passed

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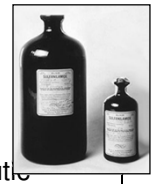
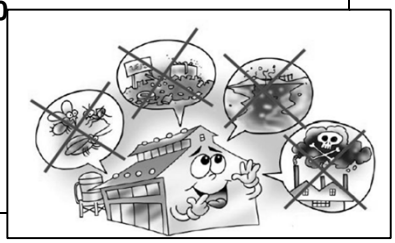
THE LAWS … & THE NEED FOR LAWS

- Sulphonamide disaster in 1937
- Similar incidents in UK for IV fluids 1972
- Haitian disaster 1997
  - 21 Code of Federal Regulations for biological therapeutic drug products
  - **Parts 210 and 211**
  - **Parts 600-680**





1941 INITIATION OF GMP

- Sulfathiaziole tablets contaminated with phenobarbital
- 1941 - 300 people died/injured
- FDA to enforce and revise manufacturing and quality control requirements
- 1941 - GMP is born

CERTIFICATE OF PURITY

This is to Certify that Dr. Kilmer's Swamp-Root, the great kidney, liver and bladder remedy, is purely vegetable and does not contain any calomel, mercury, creosote, morphine, opium, strychnine, cocaine, nitrate potash (salt-petre), bromide potassium, narcotic alkaloid, whiskey, wine or any harmful or habit producing drugs. Swamp-Root was discovered through scientific research and study by Dr. Kilmer, who graduated with honors and is now actively engaged in the practice of his profession, which calling he has successfully followed many years. {State of New York, County of Broome, } S.S. City of Binghamton, }

Jonas M. Kilmer, senior member of the firm of Dr. Kilmer & Co., of the City of Binghamton, County of Broome, State of New York, being duly sworn, deposes and says that the guarantee of purity of Swamp-Root, as described in the foregoing certificate, is in all respects true.

Jonas M. Kilmer

Subscribed and sworn to } before me April 26. 1906. }

Dr. Kilmer's Swamp-Root is not recommended for everything, but if you have kidney, liver or bladder trouble, it will be found just the remedy you need. Swamp-Root makes friends. It is bottle contains the same standard of purity, strength and excellence. You may have a sample bottle of Dr. Kilmer's Swamp-Root free by mail. If you have not already had one. When writing to Dr. Kilmer & Co., Binghamton, N. Y., be sure to mention reading this generous offer in this paper. If you are already convinced that Swamp-Root is what you need, you can purchase the regular fifty-cent and one-dollar size bottles at drug stores everywhere. Don't make any mistake, but remember the name, Swamp-Root, Dr. Kilmer's Swamp-Root, and the address, Binghamton, N. Y.

Fig. 5 1906 Certificate of Purity signed by doctor

1962 KEFAUVER-HARRIS DRUG AMENDMENTS

- Thalidomide tragedy
- Thousands of children born with birth defects due to adverse drug reactions of morning sickness pill taken by mothers
- Strengthen FDA's regulations regarding experimentation on humans and proposed new way how drugs are approved and regulated
- "Proof of efficacy" law

U. S. Department of Health, Education, and Welfare

Food and Drug REVIEW

Issued by the Food and Drug Administration

Vol. 46 November 1962 No. 11

PRESIDENT KENNEDY SIGNS NEW DRUG AMENDMENTS

Observers are, from left to right, Senator Thomas J. Dodd, Dr. Frances Kelsey, Commissioner Larrick, Senator Philip A. Hart, Senator Hubert H. Humphrey, Senator Estes Kefauver, Senator Olin D. Johnston, Under Secretary Ivan Nestingen, Congressman Leo W. O'Brien, and Congressman Kenneth A. Roberts.

On signing the Amendments on October 10, the President made the following statement:

"I am pleased to approve this bill, which is designed to provide safer and more effective drugs to the American consumer. Enactment of this legislation will help give the American consumer the protection from unsafe and ineffective drugs. It will also insure that our pharmaceutical industry will be even better equipped to provide us with the best possible drugs to be found anywhere.

"The Congress is to be congratulated in moving so quickly. Fortunately, prior to the revelation of the dangers posed by drugs like thalidomide, the foundation for legislative action on drugs had been laid down in exhaustive

(continued on next page)

Fig 6. Kennedy signing the Kefauver – Harris Drug Amendments

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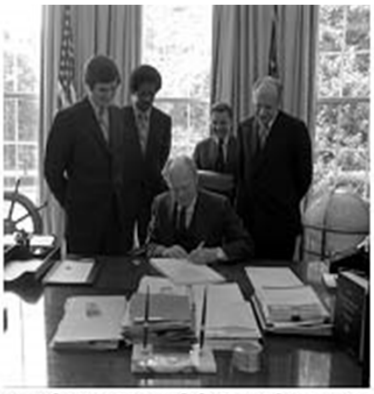
1976 MEDICAL DEVICE AMENDMENTS

- 1972 and 1973 - Pacemaker failures reported
- 1975 - hearing-Dalkon Shield intrauterine device caused thousands of injuries
- Class I, II and III medical devices – based on degree of control necessary to be safe and effective



President Gerald Ford signs the Medical Device Amendments

Fig.7 President Gerald Ford signs the Medical Device Amendments

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1980 INFANT FORMULA ACT

- 1978 - major manufacturer of infant formula reformulated two of its soy products
- 1979 - Infants diagnosed with hypochloremic metabolic alkalosis
- Greater regulatory control over the formulation and production of infant formula

Fig.8 Parody on Infant Formula Act

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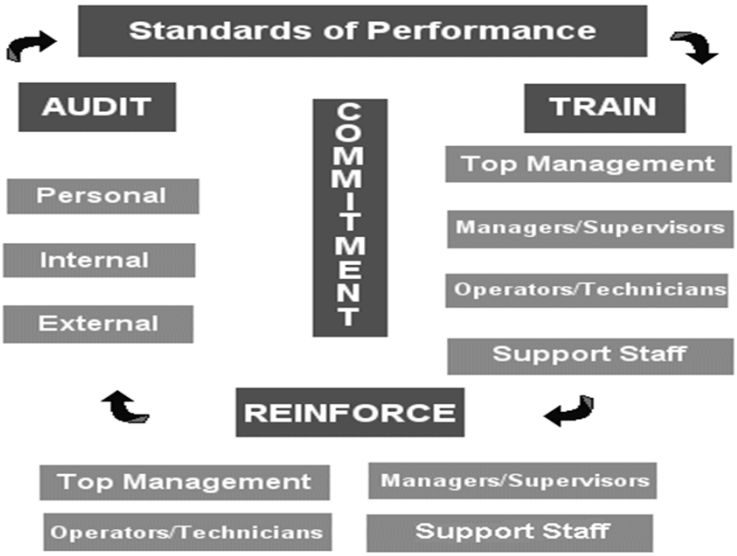
GOOD MANUFACTURING PRACTICE



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GMP HISTORY…

- first developed in 1962 congressional legislation.
- ensure that the pharmaceutical products available to the public be safe, pure, and effective.
- FDA is a Federal Agency, part of the Department of Health and Human Services.
- The basis for the development of GMP is the Federal Food, Drug, and Cosmetic Act passed by Congress in 1938. The 1962 law was an Amendment to the Federal Food, Drug, and Cosmetic Act.

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GMPS FOCUS ON:

- Raw materials
- Manufacturing process
- Adequate quality control measures during manufacture, at time of release right up to end of shelf life

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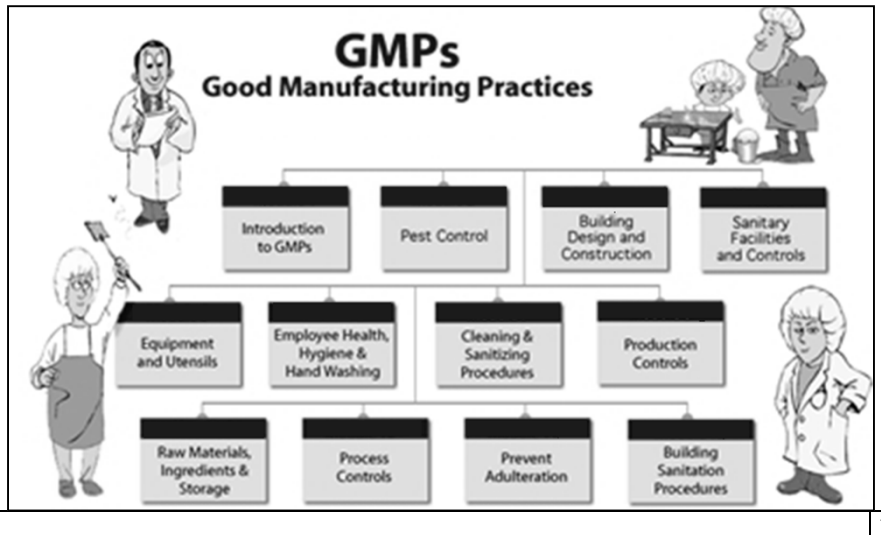
SGS INTRODUCTION TO THE GMP…



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GMP IS ….

- A set of regulations **mandated** by Govt.
- A Quality System stamp.
- Adherence to Quality Systems**.**
- Ensures Safety, purity and Efficacy

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SGS

WHY IS IT MANDATORY?

- To promote good nutrition and informed use of drugs, food, medical devices and natural health products.
- To maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

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SGS

GENERAL GUIDING PRINCIPLE OF GMP

- **The holder of an establishment license, or any operation, must ensure safety and quality.**

18

SGS

GENERAL GUIDING PRINCIPLE OF GMP

- **The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment.**

19

SGS

GENERAL GUIDING PRINCIPLE OF GMP

- **Ensure compliance.**

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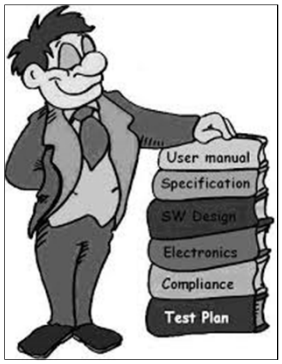
GENERAL GUIDING PRINCIPLE OF GMP

- **The system should be fully documented and its effectiveness monitored.**



Accessibility

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PHARMA FOCUSSED GUIDELINES AND REFERENCES

- **GMP applies to both Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products (FPPs)**
  - **FPP:**
    WHO Good Manufacturing Practices for pharmaceutical products: main principles. *WHO Technical Report Series, No. 908, 2003, Annex 4.*
  - **API:**
    WHO good manufacturing practices for active pharmaceutical ingredients - Annex 2, WHO Technical Report Series 957, 2010 (Based on ICH Q7)

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GOOD MANUFACTURING PRACTICES (FPP):

1. Quality assurance
2. Good manufacturing practices for pharmaceutical products
3. Sanitation and hygiene
4. Qualification and validation
5. Complaints
6. Product recalls
7. Contract production and anal
   - General
   - The contract giver
   - The contract accepter
   - The contract

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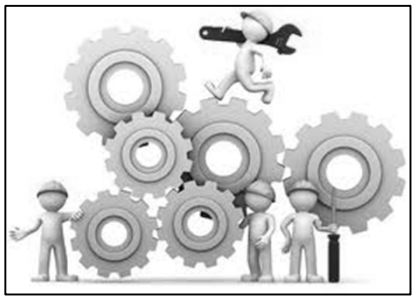
GOOD MANUFACTURING PRACTICES (CONT'D)

8. Self-inspection and quality audits

9. Personnel
   - General
   - Key personnel
10. Training



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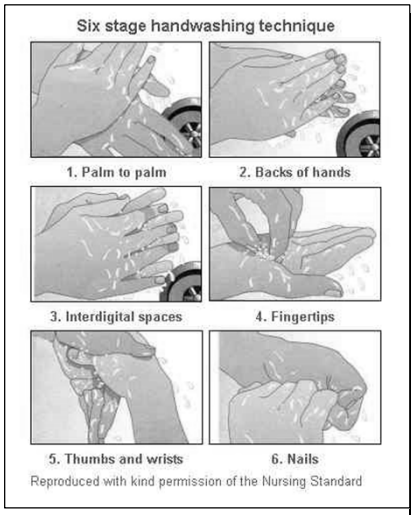
GOOD MANUFACTURING PRACTICES (CONT'D)

11. Personal hygiene
12. Premises
    - General
    - Ancillary areas
    - Storage areas
    - Weighing areas
    - Production areas
    - Quality control area
13. Equipment



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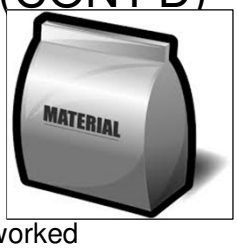
GOOD MANUFACTURING PRACTICES (CONT'D)

14. Materials
    - General
    - Starting materials
    - Packaging materials
    - Intermediate and bulk products
    - Finished products
    - Rejected, recovered, reprocessed and reworked materials
    - Recalled products
    - Returned goods
    - Reagents and culture media
    - Reference standards
    - Waste materials
    - Miscellaneous



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GOOD MANUFACTURING PRACTICES (CONT'D)

15. Documentation
    - General
    - Documents required:
      - Labels
      - Testing procedures
      - Specifications for starting and packaging materials, for intermediate and bulk products and for finished products
      - Master formulae and Batch Manufacturing Records
      - Packaging instructions and Batch Packaging Records
      - Standard Operating procedures (SOP's) and records
      - Logbooks

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GOOD MANUFACTURING PRACTICES (CONT'D)

16. Good practices in production
    - General
    - Prevention of cross-contamination and bacterial contamination during production
    - Processing operations
    - Packaging operations
17. Good practices in quality control
    - Control of starting materials and intermediate, bulk and finished products
    - Test requirements
    - Batch record review
    - Stability studies

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GMP CATEGORIES

- Sale
- Premises
- Equipment
- Personnel
- Sanitation
- Raw Material Testing
- Manufacturing Control
- Quality Control Department
- Packaging Material Testing
- Finished Product Testing
- Records
- Samples
- Stability
- Sterile Products
- Medical Gases

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QUALITY BY DESIGN

Processes

Products

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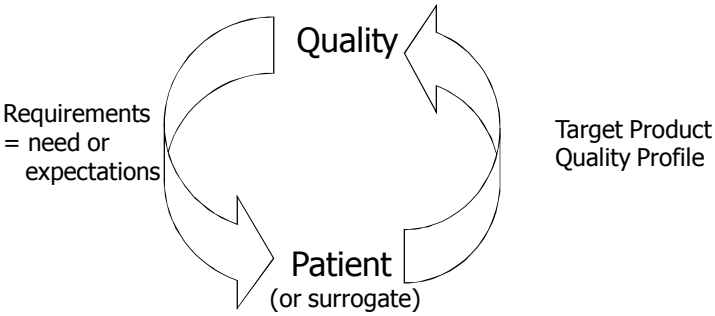
WHAT IS QUALITY?



"Good pharmaceutical quality represents an acceptably low risk of failing to achieve the desired clinical attributes."

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GMP-INTERNATIONAL

- GMPs are in effect in almost 104 countries, either as regulations, codes, directives or guidelines.
- US FDA, TGA (Australia), UK (MHRA) or Government of India.
- Australia- as Code
- UK - as Guidelines
- Europe- as Directives
- USA, Japan and Korea- as Regulations.

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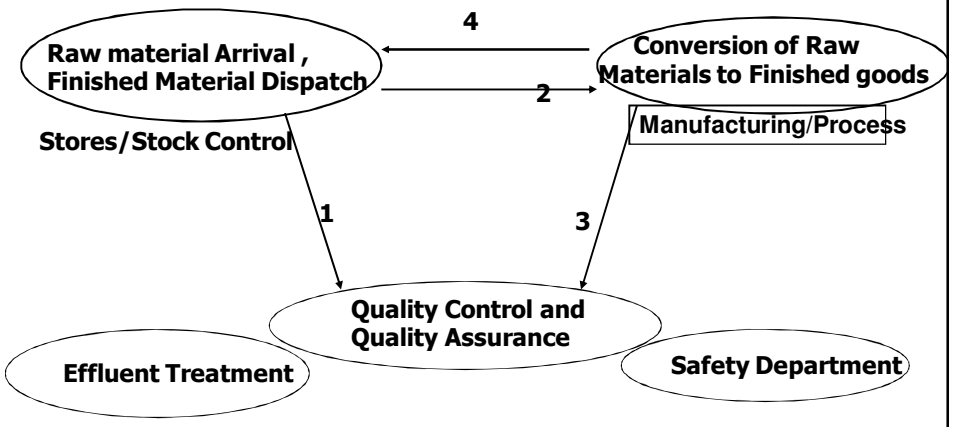
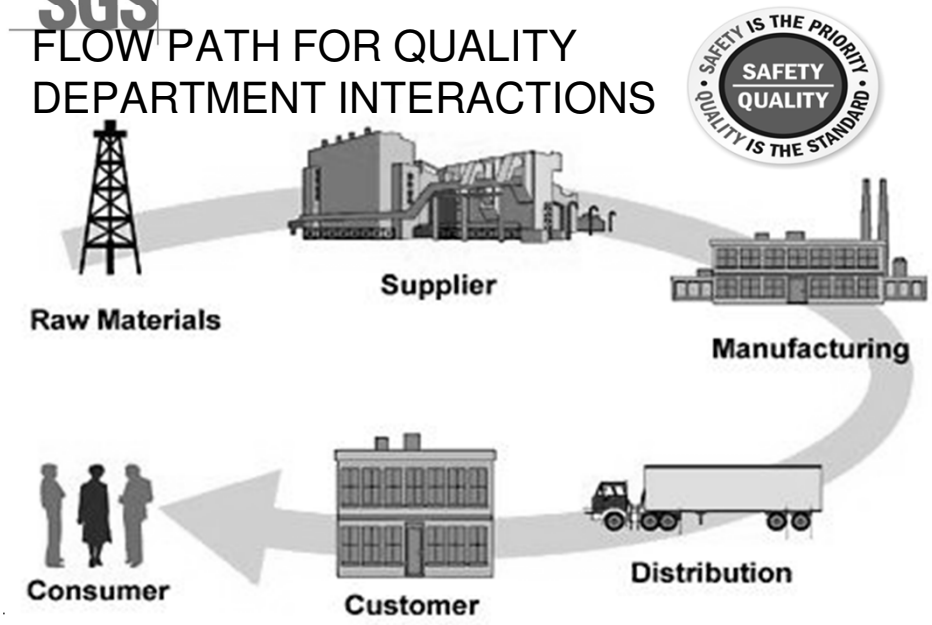
FLOW PATH FOR QUALITY DEPARTMENT INTERACTIONS



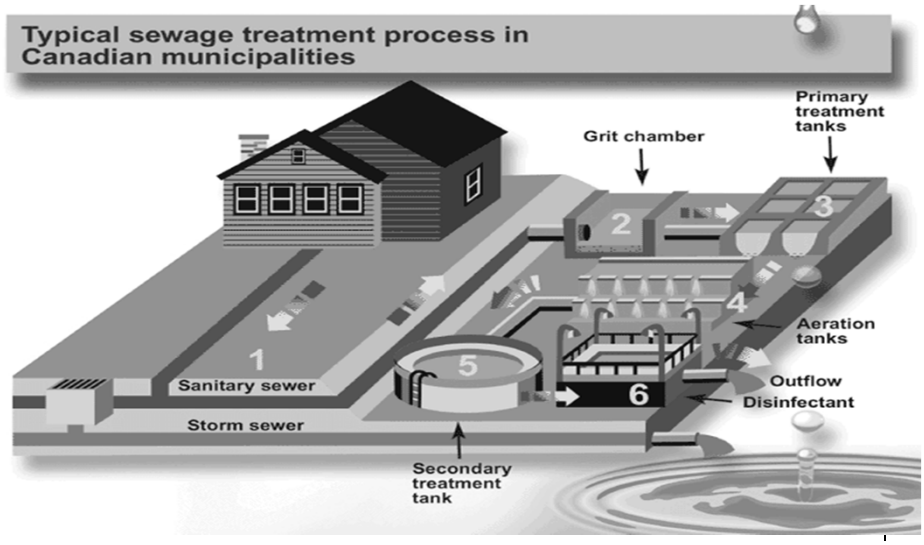
WHEN YOU NEED TO BE SURE SGS

SGS

FLOW PATH FOR QUALITY DEPARTMENT INTERACTIONS



EFFLUENT TREATMENT



GMP & QUALITY RELATIONSHIP

Quality Management

Quality Assurance

GMP

Production and Quality Control

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SGS GMP

- **Good Manufacturing Practice**
- **Good Management Practice**
- **Get More Profit**
- **Give more Production**
- **GMP Training with out tears**

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SGS GMP= CONTINUOUS URGE FOR IMPROVEMENT

- Involvement of the management

GMP= CONTINUOUS URGE FOR IMPROVEMENT

- Annual Product Quality Review

- Qua

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GMP= continuous urge for improvement

- Complaints handling

- Self-inspection

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CGMP: CAN GUARANTEE MY PRODUCTS!!

Four primary areas of concern

- **Contamination:** any substance or energy that adversely affects drug performance
- **Goof Ups:** errors of omission and commission of human origin
- **Mix Ups:** special case of human error through gross negligence and carelessness
- **Process Inconsistency:** a process that is unstable and unreliable

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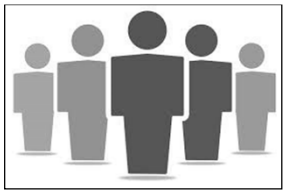

WHEN YOU NEED TO BE SURE

THE FIVE P'S

- People
- Primary materials
- Premises
- Procedures
- Processes defined and recorded

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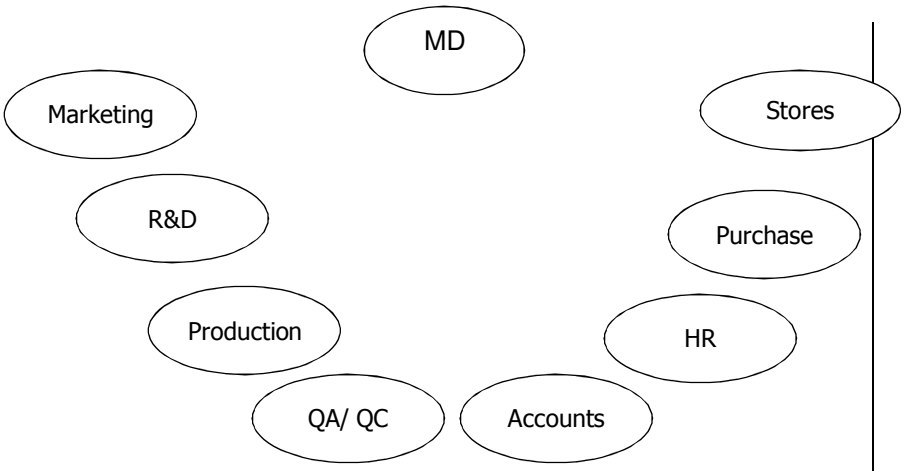
PEOPLE….

WHEN YOU NEED TO BE SURE

ORGANIZATION & PERSONNEL



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PERSONNEL: CHECK LIST

- ✓ Adequate no. of people
- ✓ Education and experience
- ✓ Proper training
- ✓ Clean clothing and protective apparel
- ✓ Practice good sanitation and health habits

46

PROTECTING YOURSELF

- Wear the clothing and protective wear identified in your risk assessment
- Laboratory coats must be kept fastened
- Don't wear sandals or open shoes
- Long hair must be tied back

47

PROTECTING YOURSELF - GLOVES

- There are many different types of protective glove
- Use the correct ones for the job you will be doing
- Remember that you need to select chemical protection gloves according to the materials and/or substances with which you will be working
- Remove your gloves before using instruments, telephone, and leaving the laboratory

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HOW TO DO A RISK ASSESSMENT?

- Determine **hazards** and evaluate **risks**
- Use all relevant **available data**
- Determine **controls** needed to minimise those risks
- **Document** the assessment
- **Agree** it with your supervisor
- **Use** those control measures

You will receive specific training on how to do this in your department

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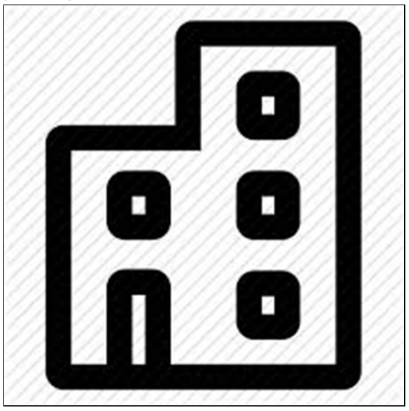
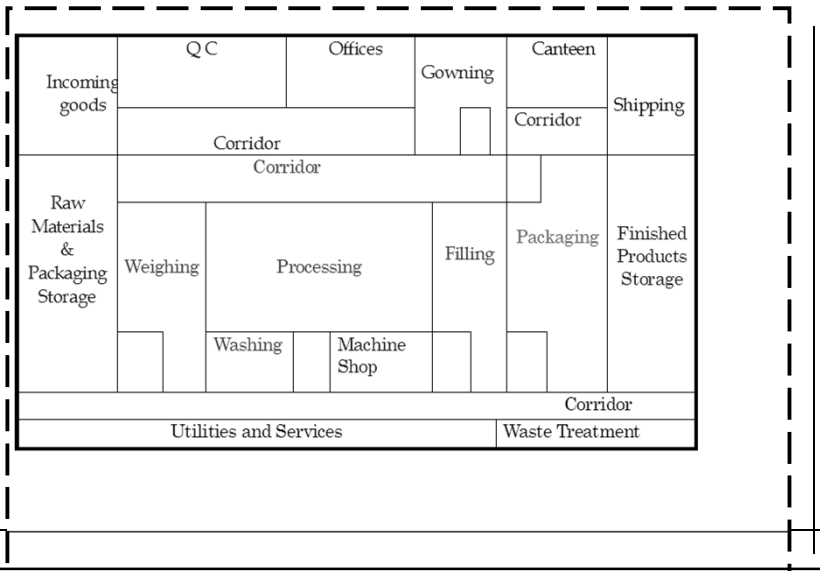
PREMISES



WHEN YOU NEED TO BE SURE



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BUILDING & FACILITY

- ✓ Suitably located to avoid product contamination and cross contamination.
- ✓ Designed and constructed for intended operations and to avoid operational errors.

✓Cleaning and maintenance

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BUILDING & FACILITY




53

UNIDIRECTIONAL FLOW: CLEAN CORRIDOR AND RETURN CORRIDOR


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SGS

PRODUCT AREAS

- Premises should preferably be laid out in such a way as:
  - To allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations, the requisite cleanliness levels,
  - To avoid crowding and disorder,
  - To allow effective communication and supervision.

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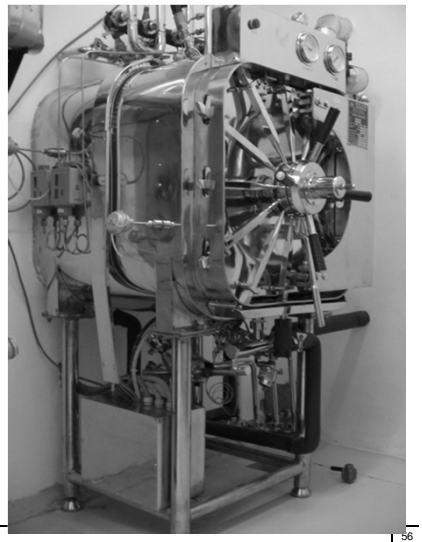
SGS

EQUIPMENT

- ✓ Proper size, design, location
- ✓ Easy to use, clean, maintain
- ✓ Inert surfaces
- ✓ Validated before being put to use.



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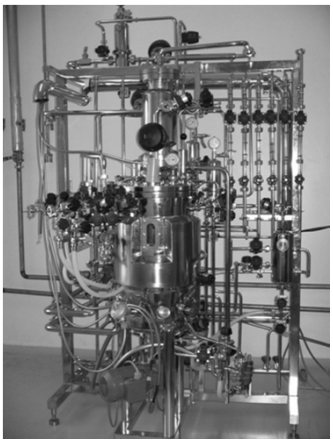
EQUIPMENT

- SOPs for
  - cleaning,
  - maintenance,
  - operations,
  - sanitization,
  - calibration
  - performance checks
  - Assignment of responsibilities



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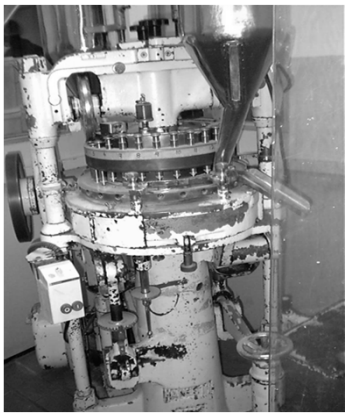
PAINT FINISH…

- Not only building paintwork must be considered but also equipment

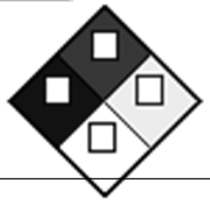


58

POOR & GOOD WINDOWS

59

Signs and Labeling



60

GENERAL HAZARDS

- Fire
- Breakage of glassware
- Sharps
- Spillages
- Pressure equipment & gas cylinders
- Extremes of heat & cold
- Chemical hazards
- Biological hazards
- Radiation

And many more!

61

WHEN IN DOUBT – ASK!!!

- Do not carry out a new or unfamiliar procedure until you have been fully trained & understand the precautions necessary for safe working

DO NOT GUESS!!!!

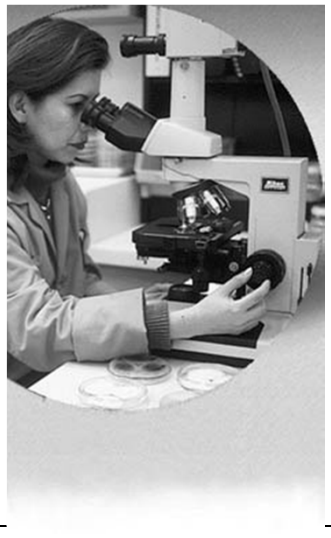
62

WHEN YOU NEED TO BE SURE SGS

SGS

LAB CONTROLS

- Well equipped Quality Control Laboratory with well trained and experienced staff
- Product specifications
- Appropriate equipments which are calibrated, qualified and maintained.



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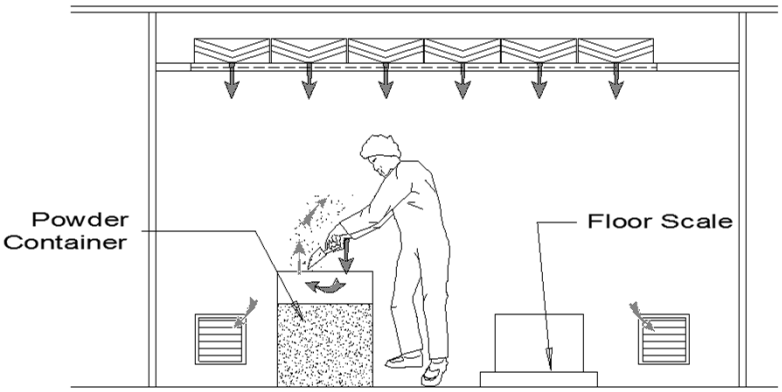
SAMPLING PROCEDURE



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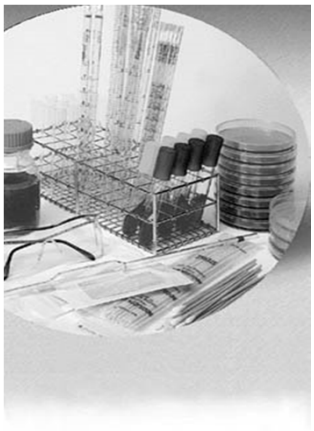
LAB CONTROLS



- Validated analytical methods
- Well defined and documented test methods
- Approved and standardized reagents and solutions
- Documented data including calculations
- Archiving of all records and data for a stipulated period.
- Product stability studies
- Production Process
- Environmental monotoring and controls

66

STERILE PRODUCTS PACKAGING

- Sterile Products
  - Packaged in separate enclosed area by trained personnel using method to ensure sterility



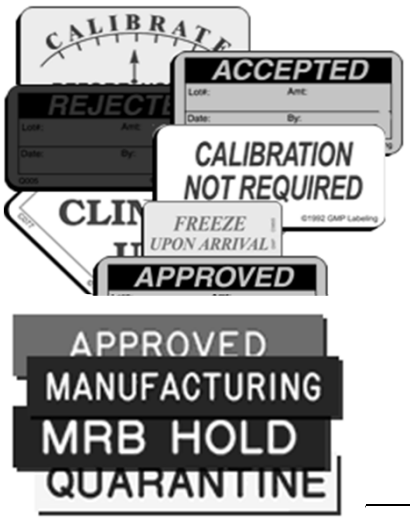

67

PACKAGING AND LABELING CONTROL

- Labeling reqd : avoid mix ups and cross over.
- Every container's identity.
- Labels must be signed by authorized personnel.
- Warehouse containers should indicate the status of the material, Released, rejected, on hold etc.
- Colour coding helps identify container status from a distance.

68

LABELING



- GMP Labeling System offers standard roll labels in a wide variety to make it easier to comply with GMP regulations and ISO 9000 requirements.
- GMP labels help you identify components, pilot batches, raw materials, in-process materials, and areas in your laboratory and in production. GMP labels are designed in distinctive shapes, sizes, colors, and color coded titles to prevent lost identities, mix-ups and errors.

69

PACKAGING

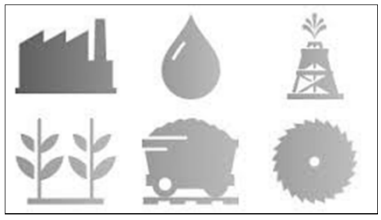
- Retains the quality of the product during its shelf life.
- Should sustain all weathers and climates
- Should have all details identifying the product and tracing it to its origin
- The packing and labeling material is in the control of authorized personnel.

70

71

PACKAGING

72



PRIMARY MATERIALS

WHEN YOU NEED TO BE SURE SGS

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MATERIAL HANDLING

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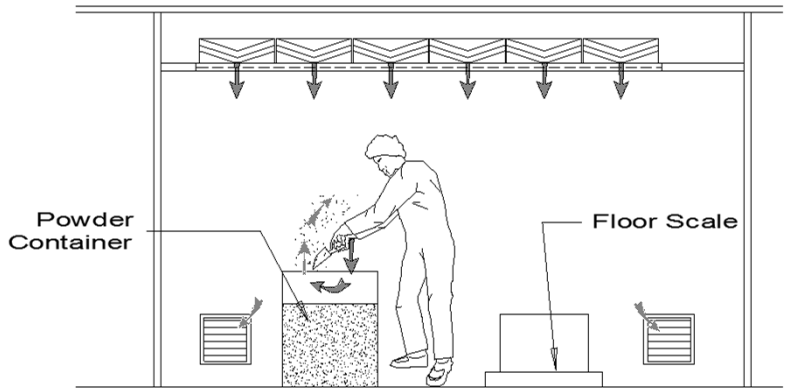
SAMPLING PROCEDURE



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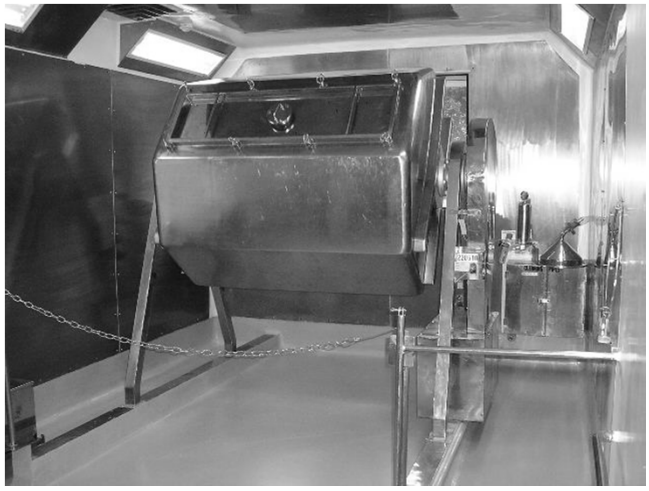
WEIGHING

76

BLENDING



77

AHU

78

RAW MATERIALS

- Proper conditions (temperature, humidity)
- Frozen raw materials kept at - 4^{O}C or below (do not allow thawing)
- Appropriate stock rotation
- Pest control programs
- Sufficient space

79

END PRODUCTS

- Stored and handled to prevent deterioration
- Returned, defective products identified and isolated
- Stock rotation
- Adequate lighting
- Pest control programs
- Cleaning and sanitizing programs
- Well ventilated

80

SAMPLES AND STABILITY

- Samples
  - Retain samples of each lot of raw material and finished product for specified period of time
- Stability
  - Establish the length of time in which the product meets all specifications
  - Monitor the drug for this period of time

PRODUCT RECALL PROCEDURES

- Written and tested product recall program
- Written recall procedures
  - person responsible- recall team
  - step-by-step procedures described
  - product traceability- product coding - distribution records
  - means of notifying customers, retailers or wholesalers
  - means of coordinating recall with regulatory agencies
- Addressing the complaint and follow ups
- Adverse experience reports

82

FDA 101: PRODUCT RECALLS

First Alert
FDA hears about product problems through company notification, agency inspections and adverse event reports, and through CDC.

Alerting the Public
FDA posts regular updates about recalls to its Web site, and all recalls appear in the agency's weekly Enforcement Reports.

Effectiveness Checks
FDA reviews all of a company's corrective actions to determine when a recall is complete.

83

PROCESSES DEFINED AND RECORDED

WHEN YOU NEED TO BE SURE

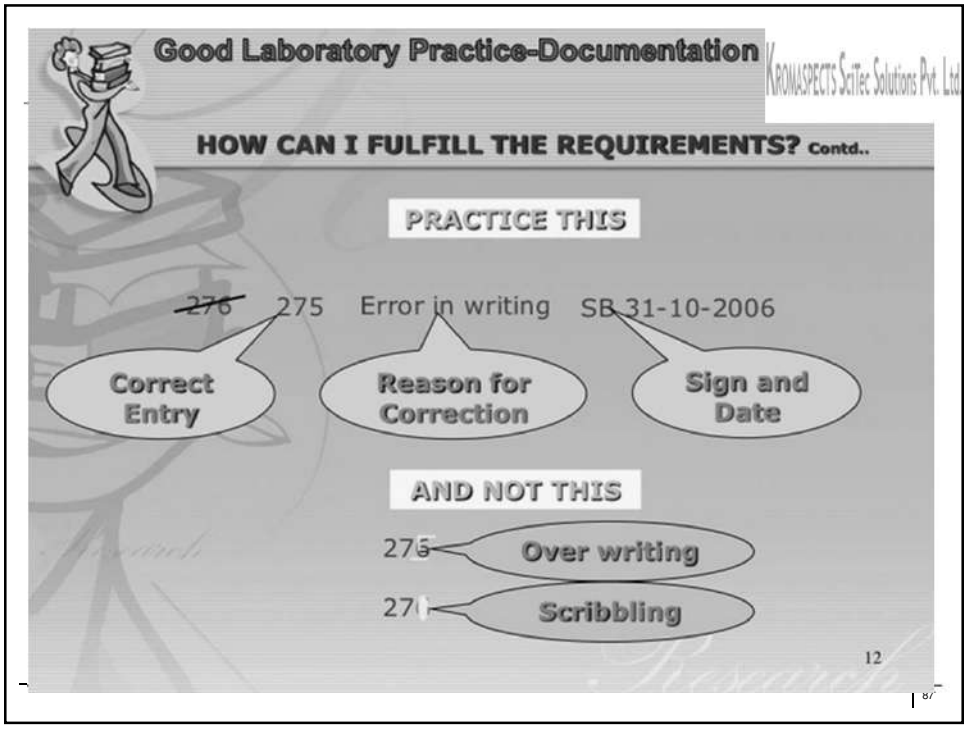
DOCUMENTATION

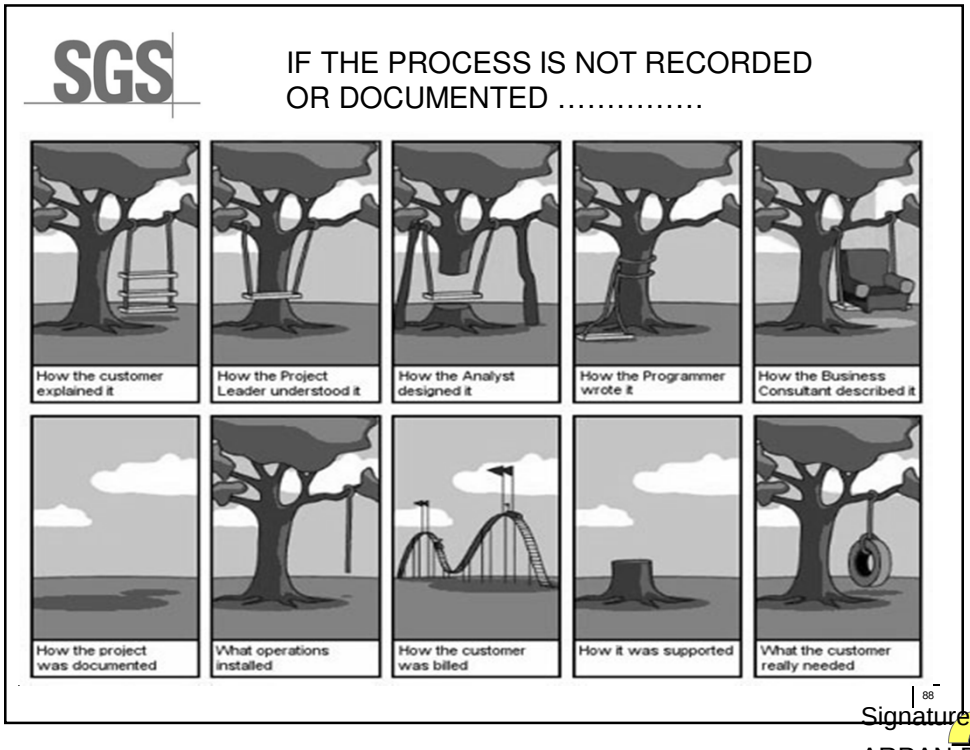
- Quality Manual - policy statements on the way a company intends to carry out its business
- Operating Procedures - what a company does and how it achieves stated policies
- Support Documentation - how a company carries out what it says it does (in detail)

85

DOCUMENTATION

Quality Pyramid





GMP DOCUMENTATION

- Required by FDA, "If it's not documented, it didn't happen..."
- Required for procedures.
- Validation, documentation required for critical processes to show results meet quality attributes.

89

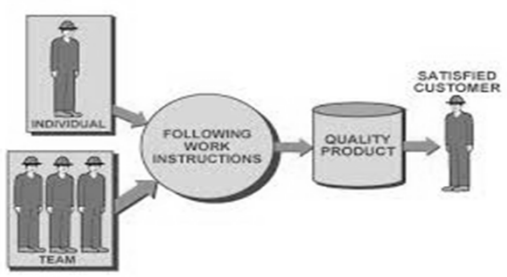
SOP (STANDARD OPERATING PROCEDURE)

- **What to do, who does it and when**
- **Not static; continuously adjusted**
- **Simple**
- **Training aid**
- **Prevent 'subject-to-change-without-notice' situation**
- **Provide written standard for audits**
- **Effective;detail,simplicity and practicality**

90

SUPPORT DOCUMENTS

- Working Instruction
- Codes of Practice
- User Manuals
- Technical Documentation
- Job Description
- Job Specification
- Forms
- Checklists



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RECORDS AND REPORTS

92

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CODING ,NUMBERING AND STORING

93

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DEVIATION CONTROL
AND
CHANGE CONTROL

94

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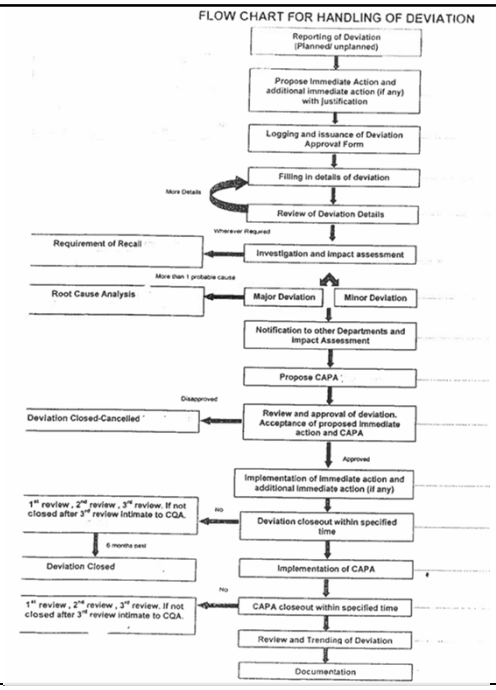
FLOW CHART FOR HANDLING OF DEVIATION



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Form ID:	Change ID:	Item ID:
Item Location:		
Change Initiator:	*Enter name.*	*Date of request.*
Description of Change:	*Enter a summary and a reason for the change and the business benefit.*	
Change Priority:	High O Medium O Low O	
Latest Acceptable Date:	*Only necessary if the change is time critical.*	
Impact Assessment:	*Describe the technical impact, on the individual item and on the entire network, typically done by the validation group.*	
Risk Assessment:	Risk: Likelihood: Severity: Recovery:	
Test Plan: *(Validation Group)*	*Describe test efforts.*	
Regulatory Notification Required:	Yes O No O *(Done by QA)*	
Change Approval:	Accepted O Rejected O Comments or reasons for rejection:	
Signatures: Laboratory Mgt. QA Mgt.	Name: Signature: Date:	

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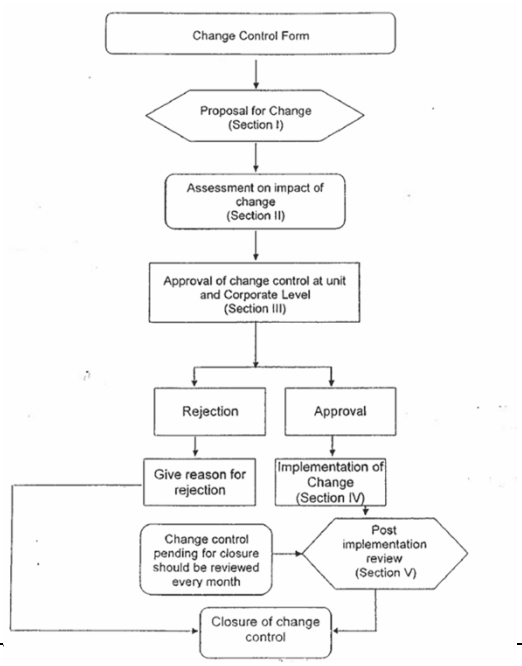

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98

SELF-INSPECTION

- Purpose is to evaluate whether a company's operations remain compliant with GMP
- **The programme should**
  - *cover all aspects of production and quality control*
  - *be designed to detect shortcomings in the implementation of GMP*
  - *recommend corrective actions*
  - *set a timetable for corrective action to be completed*
- **Should be performed routinely**
- **Also on special occasions such as**
  - *Recalls*
  - *Repeated rejections*

99

SELF-INSPECTION (CONT'D)

- Performed by team appointed by management, with:
  - authority
  - sufficient experience, expertise in their own field. knowledge of GMP
  - may be from inside or outside the company
- Frequency should normally be at least once a year
  - May depend on company requirements
  - Size of the company and activities

100

SELF-INSPECTION (CONT'D)

- Report prepared at completion of inspection, including:
  - results
  - evaluation
  - conclusions
  - recommended corrective measures
- Follow-up action
  - Effective follow-up programme
  - Company management to evaluate b the report and corrective actions

101

- Response to Inspector's queries during the course of inspections
- Inspection outcome and its consequences (with examples)
- Short notice and Surprise inspections
- All time readiness and its importance

102

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103

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SUMMARY-CGMP

- FDA-Mandated
- Part of our commitment to quality
- Help us ensure safe, effective, consistent product
- Is everyone's responsibility

104

10 GOLDEN RULES OF GMP

1. **Be "fit" for your job**
2. **Stay "fit" for your job**
3. **Have plant and machinery always "fit" for intended use**
4. **Maintain the plant and machinery always fit for intended use**
5. **Have a stable and capable process**
6. **Validate your process**
7. **Have written operating procedures for your work**
8. **Follow the written operating procedures in your work**
9. **Cross check and report your data as you do it**
10. **Audit for continued conformance**

105

BEYOND GMP

- Reduce pollution -→ Zero discharge
- Adaptation of environment friendly methods
- Consideration for better & healthier life tomorrow
- Consideration of ethics in life
- One should begin with end in mind otherwise it will be the beginning of the end

FOLLOW GMP

AND ENSURE

A

QUALITY PRODUCT

107

GMP QUESTION AND ANSWERS…

108

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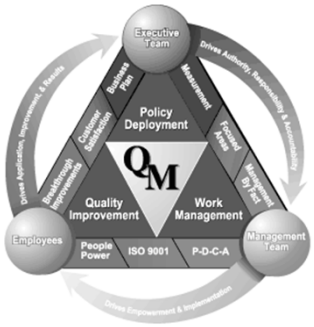
REFERENCES AND CREDITS

ALL LOGOS, IMAGES AND DATA BELONG TO THEIR RESPECTIVE WEBSITES AND REFERENCES

SGS

Topic: "Introduction to Quality Management"



References:- ISO 9000 :2005 (E)

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Quality Management

What is Quality after all?

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Quality Management

ISO 9000 : 2000 defines Quality as:

" Degree to which a set of inherent characteristics fulfills requirement"

3

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Quality Management

Which is of a better Quality?

4

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Quality Management

ISO 9000 : 2000 defines the Quality management as:

" coordinated activities to direct and control an organization with regard to quality"

Total Quality Management

5

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Quality Management

ISO 9000 : 2000 defines the Quality control as:

" Part of quality management, focused on providing confidence that quality requirements will be fulfilled"

6

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Quality Management

ISO 9000 : 2000 defines the Quality Control as:

" Part of quality management, focused on fulfilled quality requirements"

7

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Quality Management

Quality Management Principles

Customer focus

Leadership

Involvement of people

Process Approach

System Approach

Continual Improvement

Factual Approach to Decision Making

Mutually Beneficial Supplier Relationship

8

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Quality Management

Principle 1

Customer focus

CUSTOMER FOCUS runs business

Organizations depend on customers

Determine customer needs & expectation

⇩

Requirements

⇩

Customer Satisfaction

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Quality Management

Principle 2 - Leadership

Leader establish unity of purpose, direction and internal environment in which people become fully involved

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Quality Management

Principle 3 - Involvement of people

- *People are the essence of the organization*
- *Their full involvement enables using their abilities to the benefit of the organization.*

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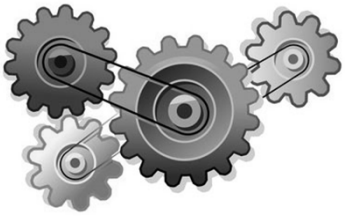
Quality Management



Principle 4 - Process approach

A desired result is more effectively achieved when resources and activities are managed as a process.

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Quality Management

Principle 5 - System approach

Identifying , understanding and managing a system of interrelated process for a given objective contributes to effectiveness and efficiency.

13

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Quality Management

Principle 6 – Continual Improvement

Continual improvement is a permanent objective of the management

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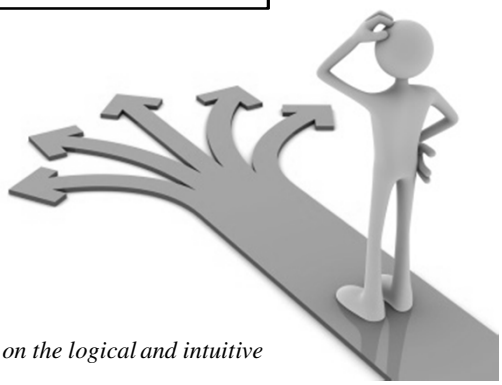
Quality Management

Principle 7– Factual approach to decision making



Effective decisions are based on the logical and intuitive analysis of data and information.

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Quality Management

Principle 8– Mutually beneficial supplier relationship

Mutually beneficial relationship between organization and its suppliers enhance the ability of organization to create value.

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THANK YOU FOR YOUR ATTENTION

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Topic: "Introduction to Audits"

References:- ISO 9000 :2005 (E)

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Introduction to Audits

"Systematic, Independent and documented process of obtaining audit evidence and evaluating it objectively to determine the extent of which audit criteria are fulfilled"

2

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Introduction to Audits

Purpose of Audit

- ✓ *To determine conformity.*
- ✓ *To determine the effectiveness.*
- ✓ *To provide opportunity to improve.*
- ✓ *To meet the regulatory requirements.*
- ✓ *For certification.*

3

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Introduction to Audits

Reason to conduct Audit

- ✓ *New Supplier.*
- ✓ *Regular review of suppliers.*
- ✓ *Contractual requirement.*
- ✓ *Changes in system.*
- ✓ *Increased orders.*
- ✓ *Quality Problems.*

4

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Introduction to Audits

Benefits

- ✓ *Give the management confidence.*
- ✓ *Give customers confidence.*
- ✓ *Observe operational problems.*
- ✓ *Provide opportunity for improvement.*
- ✓ *Provide feedback for CAPA.*

5

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Introduction to Audits

Initial Document review & Benefits

- ✓ *Understand the system*
- ✓ *Assist planning*
- ✓ *Identify need for specialist skills.*
- ✓ *Identify problems*
- ✓ *Provide opportunity to fill the gaps*
- ✓ *Assess readiness*

6

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Introduction to Audits

Conformance Audit or Implementation Audit

?=

Work Practices

7

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Introduction to Audits

ISO 10011 guidelines for Auditing quality system

Part – 1 : Auditing.

Part – 2 : Qualification criteria for quality system auditors.

Part – 3 : Management of audit programmes.

8

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Introduction to Audits

Auditing

Audit objectives.

Roles and Responsibilities of Auditors, Clients, Auditees.

Auditing.

Audit documents.

Audit completion.

Corrective action follow - up

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Introduction to Audits

Qualification criteria for quality system Auditors

Education.

Training.

Experience.

Personal attributes.

Management Capabilities.

Language.

Selection of lead auditor.

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Introduction to Audits

Management of audit programmes

Organization.

Standards.

Qualification of Staff.

Monitoring of Auditors performance.

Operational factors.

Joint audits.

Code of ethics.

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Introduction to Audits

Fundamentals of Auditing – General Principles

Independence	–	The basis for the understanding & reliability.
Ethical conduct	–	The foundation of integrity
Fair presentation	–	Reporting truthfully and accurately
Evidence	–	The rational basis for conclusions
Due care	–	Reasonable care in all matters.

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Introduction to Audits

Auditing Activities

Initiating the audit.

Initial document review.

Preparing for the on- site audits.

On – site auditing activities.

Reporting on the audit.

Audit completion.

Audit follow – up.

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THANK YOU FOR YOUR ATTENTION

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Topic: "Performing an Audit"

Internal Audit

References:- ISO 9000 :2005 (E)

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Performing an Audit

Gathering information

- ✓ Interviewing
- ✓ Body Language
- ✓ Document review
- ✓ Observation

2

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Performing an Audit

Document review

- ✓ Quality Manual.
- ✓ SOPs.
- ✓ Work instructions.
- ✓ Records.

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Performing an Audit

Sample of record

- ✓ No time to check everything.
- ✓ Select representative sample.
- ✓ No set percentage.
- ✓ Representation of actions.
- ✓ Cover relevant period.
- ✓ Look at controls.

4

Performing an Audit

Observations

- ✓ Keep observing the physical evidence:
  - ➢ Products.
  - ➢ Equipments.
  - ➢ Instructions.
  - ➢ Conditions.
  - ➢ Operations.

5

Performing an Audit

Observations

- ✓ If u had checked a Gauge:
  - ➢ What is it used for ?
  - ➢ Need it be calibrated?
  - ➢ Was it calibrated?
  - ➢ Is there a record.
  - ➢ What is the reading
  - ➢ Is the reading within the acceptance criteria

6

Performing an Audit

Audit Trial:

- Select Job (s).
- Follow it through.
- Select pertinent records.
- Were all activities performed?
- Were the procedures or plans followed?

7

Performing an Audit

Identification and control of processes their sequence and interaction is critical for effective quality Management.

8

Performing an Audit

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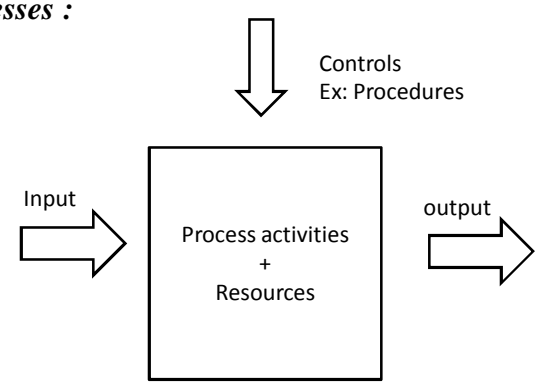
Processes :



9

Performing an Audit

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Preparing to audit process

- Identify the purpose.
- Ownership.
- Identify input.
- Identify indented output.
- Establish the flow of activities.
- What resources are used?
- What are the controls?
- How it is monitored?
- Responsibilities and authorities?

10

Performing an Audit

Audit the System:

- Follow the process through.
- Select pertinent records.
- Were all activities performed?
- Were the control effective?
- Are the intended outputs achieved?
- Identification?
- Status with respect to measurement and monitoring?
- Storage location & conditions?

11

Performing an Audit

Always take notes:

- Explain the need to take notes to auditee.
- Make your notes:
  - Comprehensive.
  - Accurate.
  - Precise.
  - Legible.

12

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THANK YOU FOR YOUR ATTENTION

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Topic: "Internal Audit Management"

Internal Audit

References:- ISO 9000 :2005 (E)

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Internal Audit Management

- ✓ Audits are expensive.
- ✓ Audits must be well managed.
- ✓ Audit must not be carried out "by surprise"
- ✓ Always agree mutually convenient dates well in advance.

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Internal Audit Management

- Gathering Information
- Planning & Preparations
- Opening Meeting
- Audit
- Liaisoning Meeting
  Closing Meeting
- Follow - up

3

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Internal Audit Management

Auditing by areas

versus

Auditing by department

4

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Internal Audit Management

Audit the system

- ✓ Mapping the system.
  - ❑ Processes
  - ❑ Input & Outputs
  - ❑ Controls
  - ❑ Sequence
  - ❑ Interactions
- ✓ Always agree mutually convenient dates well in advance.

5

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Internal Audit Management

How to programme internal audits?

- ✓ Consider:
  - ❑ Importance of activity.
  - ❑ Status of activity.
  - ❑ Results of previous audits.
  - ❑ Minimize disturbance.
  - ❑ Staff availability.

6

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Internal Audit Management

Four Phases – Typical Time Allocation

- Preparation 40%
- Performance 40%
- Reporting 10%
- Follow – up 10%

7

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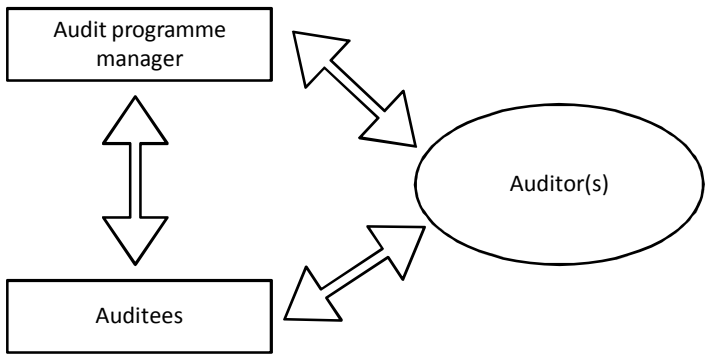
Internal Audit Management



8

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Internal Audit Management

Brief from audit programme manager:

- Area to be audited.
- Scope of the audit.
- Reason for the audit.
- Dates, duration, size of team.

9

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Internal Audit Management

Audit Scope:

- Boundaries of the Audit
  - ✓ Locations.
  - ✓ Parts of Organisation.

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Internal Audit Management

Information on the area to be audited

- What do they do?
- How big are they?
- Complexity of operations

11

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Internal Audit Management

Planning

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- Determine amount of work.
- Prepare plan.
- Prepare working documents.
- Keep auditee advised , agree date and time.

12

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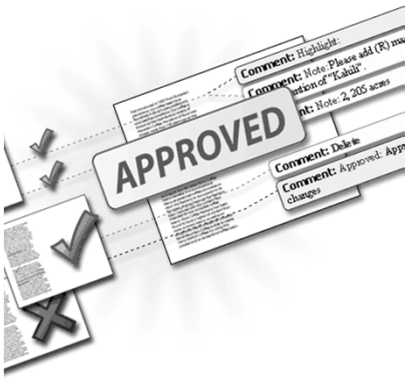
Internal Audit Management

Prepare working documents

- Checklist
- Forms
- Standard
- Guidelines



13

SGS

Internal Audit Management

Notify the auditee – give:

- Audit Plan
- Timetable
- Checklist

14

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Internal Audit Management

Meetings:

- ❑ Opening Meeting
- ❑ Closing Meeting
- ❑ Team Liaison Meeting

15

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Internal Audit Management

Meetings:

- ❑ Be prepared.
- ❑ Have agenda ready.
- ❑ Take note of attendees.
- ❑ Seating plan

Manage the time!

16

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Internal Audit Management

Opening & Closing Meetings:

- Be prepared on Time
- All team participants
- Area Management
- Team leader chairs the meeting

17

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Internal Audit Management

Opening meeting agenda:

- Introduce the team.
- Reason, Scope and Criteria.
- Review audit plan and methods.
- Explain about sampling.
- Confidentiality.
- Method of reporting.
- Grading of NCR's.
- Safety requirements.
- Questions.

18

Internal Audit Management

Team Liaison meeting :

- To ensure smooth and effective progress of the audit
- To ensure audit scope is covered.
- To collate the findings.
- To review nonconformance's.

19

Internal Audit Management

Team Liaison meeting :

- Prepare for the closing meeting.
- Review and collate the findings.
- Discuss recommendations.
- Prepare final reports.

20

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Internal Audit Management

Closing meeting agenda :

- Thank the auditee and reintroduce the team.
- Recap reason, scope and criteria.
- Report the observations, positive and negative.
- Disclaimers
- Overall Summary.
- Questions & Answers.
- Corrective actions & time - scale
- Follow - up

21

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Internal Audit Management

Follow – up action

- At agreed time
- Review of documentary evidence.
- Re- Audit on the side.
- Only review of corrective actions.
- Don't start it all over again.

22

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Internal Audit Management

Follow – up documentary evidence

- Record.
- Training certificates.
- Amended procedures.
- Photographs.
- Videos.

23

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Internal Audit Management

What if they are late?

Give them more time if possible!!!

24

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Internal Audit Management

What if it still not done?

Escalate!

25

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THANK YOU FOR YOUR ATTENTION

26

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Topic: "Writing Nonconformity Report"

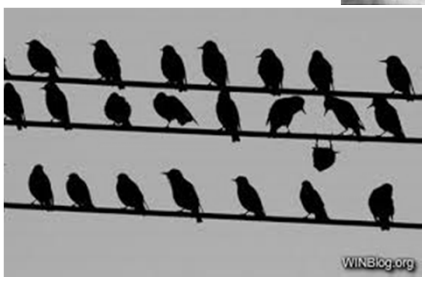
References:- ISO 9000 :2005 (E)

SGS

Nonconformity Report

Nonconformity :

" Nonfulfilment of a requirement"



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SGS

Nonconformity Report

NCR

- ✓ Report what was wrong
- ✓ Explain the requirement that was contravened
  - ❑ To assist investigation.
  - ❑ As self check, to avoid " inventing the requirements.

3

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Nonconformity Report

Exercise - 1

Production department, block – k , morning shift 4 out of 18 operators seen not wearing head gear (Helmets). Helmets are available at the entrance area.

SOP 22 requires that all personnel entering production must wear Helmets. Instruction is also displayed.

4

SGS

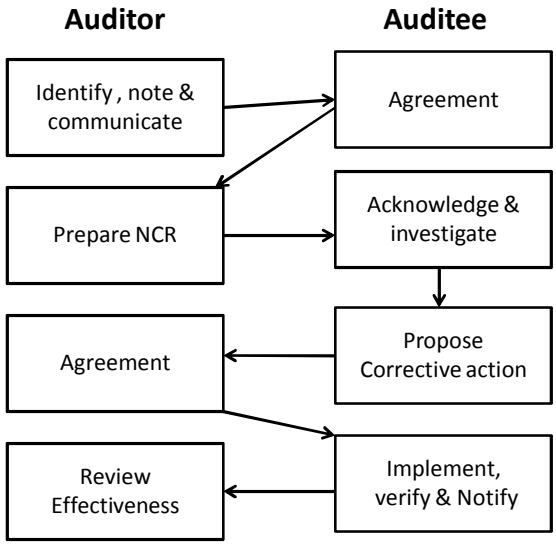
Nonconformity Report

- ✓ Area : Production Block - K
- ✓ Problem: During the morning shift 4 out of 18 operators were not wearing head gear.
- ✓ Requirement (s): Production personnel , as per the clause / SOP, requires that all the personnel in production must wear helmets
- ✓ Category: Minor
- ✓ Sign & date:
- ✓ Acknowledgment:

5

SGS

Nonconformity Report



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THANK YOU FOR YOUR ATTENTION

7

Delegate Attendance Record

Course:	
Dates:	
Location:	

Lead tutor:		**Sign:**		**Date:**	
Support tutor:		**Sign:**		**Date:**	
Observer:					

	Delegate name: (AS YOU WISH IT TO APPEAR ON YOUR CERTIFICATE)	**Day 1** (DELEGATE SIGNATURE REQUIRED)	**Day 2** (DELEGATE SIGNATURE REQUIRED)	**Day 3** (DELEGATE SIGNATURE REQUIRED)	**Day 4** (DELEGATE SIGNATURE REQUIRED)	**Day 5** (DELEGATE SIGNATURE REQUIRED)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Signature Not Verified

ARPAN BHARDWAJ
E=ARPANBHARDW
AJ11@GMAIL.COM,

Delegate Attendance Record

Course:	
Dates:	
Location:	

Lead tutor:		**Sign:**		**Date:**	
Support tutor:		**Sign:**		**Date:**	
Observer:					

	Delegate name: (AS YOU WISH IT TO APPEAR ON YOUR CERTIFICATE)	**Day 1** (DELEGATE SIGNATURE REQUIRED)	**Day 2** (DELEGATE SIGNATURE REQUIRED)	**Day 3** (DELEGATE SIGNATURE REQUIRED)	**Day 4** (DELEGATE SIGNATURE REQUIRED)	**Day 5** (DELEGATE SIGNATURE REQUIRED)
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Signature Not Verified

ARPAN BHARDWAJ
E=ARPANBHARDW
AJ11@GMAIL.COM,

Delegate Post Course Evaluation Questionnaire

Course title: …….. **Course date**: ……..

Course location: ……... **Course tutor**: …….

About you (Optional)

Name:.....……**Email:** ……..…….....

Company name: ……..**Job title:** ……..…….....

Would you like to receive further information on courses? YES / NO (if YES please complete name & email details above)

About the Course

Please rate, the training you have just received from SGS on a scale from 1 (being poor/not at all) to 4 (being excellent/completely)*:*

How fully were the course objectives explained?	❑ 4	❑ 3	❑ 2	❑ 1
How well was the course structured?	❑ 4	❑ 3	❑ 2	❑ 1
How well balanced was the mix of lecture and delegate activities?	❑ 4	❑ 3	❑ 2	❑ 1
How valuable did you find the workshops?	❑ 4	❑ 3	❑ 2	❑ 1
Were the course objectives fully met?	❑ 4	❑ 3	❑ 2	❑ 1
Were your learning objectives fully met?	❑ 4	❑ 3	❑ 2	❑ 1

Was the course duration:

- ❑ About right
- ❑ Too short
- ❑ Too long

If you answered too short or too long, please explain why?

……

……

……

About the Tutor

Please rate the training you have just received from SGS on a scale from 1 (being poor/not at all) to 4 (being excellent/completely)

The standard of presentation	❑ 4	❑ 3	❑ 2	❑ 1
Were your questions answered clearly & concisely?	❑ 4	❑ 3	❑ 2	❑ 1
The level of the tutor's knowledge	❑ 4	❑ 3	❑ 2	❑ 1

About the Course Materials

Please rate the training you have just received from SGS on a scale from 1 (being poor/not at all) to 4 (being excellent/completely)

Were the handouts and course manual informative?	❑ 4	❑ 3	❑ 2	❑ 1
Were the visual aids helpful?	❑ 4	❑ 3	❑ 2	❑ 1

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Delegate Post Course Evaluation Questionnaire

About the venue

Please rate the training you have just received from SGS on a scale from 1 (being poor/not at all) to 4 (being excellent/completely)

What did you think about the standard of training facilities?

About the room	❑ 4	❑ 3	❑ 2	❑ 1
About the environment	❑ 4	❑ 3	❑ 2	❑ 1
Were the food & refreshment of a high standard?	❑ 4	❑ 3	❑ 2	❑ 1

General

Please rate the training you have just received from SGS on a scale from 1 (being poor/not at all) to 4 (being excellent/completely)

Overall the enjoyment of the course	❑ 4	❑ 3	❑ 2	❑ 1
Overall, the service you received from SGS Training	❑ 4	❑ 3	❑ 2	❑ 1

Please add any further comments that you feel necessary for the development of our services:(*For example, please describe why you scored any of the questions with a 1, poor).*

……

……

……

.....

Have you used an SGS website in the past 3 months? **YES / NO**

If you used an SGS website, what did you use it for:

- ☐ Contacting SGS to reserve a place on a training course
- ☐ Training course prices
- ☐ Finding the contact details (addresses and phone numbers) of SGS offices to book a training course
- ☐ Learning about specific SGS training courses
- ☐ Getting information about SGS offices and training centres
- ☐ General browsing and research
- ☐ Other – please specify.....

.....

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THANK YOU

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